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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/227,881	01/11/99	NGUYEN	T 07425.0057

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EXAMINER	
SHIBUYA,M	
ART UNIT	**PAPER NUMBER**
1635	11

DATE MAILED: 09/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/227,881	Applicant(s) NGUYEN ET AL.
	Examiner Mark L. Shibuya	Group Art Unit 1635

☒ Responsive to communication(s) filed on *Jun 13, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-90* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-90* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, 54-69, 74-77, 82-84, 85-89, and 90 drawn to methods for diagnosing glaucoma and steroid sensitivity and prognosing glaucoma, methods comprising detecting the presence or absence of the characteristic TIGRmt11 sequence variation comprising contacting, with a sample, a labeled nucleic acid comprising SEQ ID NO: 33, or regions thereof; a method for detecting the specific binding of a molecule to a nucleic acid comprising providing a nucleic acid comprising a nucleotide sequence selected from the group consisting of one of SEQ ID NO: 1-3 or 34, and a fragment of SEQ ID NO: 1-3 or 34 that possess a functional regulatory region; a method for detecting TIGRmt11 sequence variation comprising amplification of a region containing the **T to C** substitution of the TIGRmt11 sequence variant and a kit thereof; a method for detecting polymorphism in the 5' flanking region of a TIGR gene, comprising selecting amplification reaction primers from the group consisting of nucleotide sequence SEQ ID NO: 6-25, or 35 or complements thereof, nucleotides from a fragment of SEQ ID NO: 6-25 or 35 or complements thereof, and nucleotide sequences from an about 18 to an about 60 nucleotide fragment of the 5' flanking sequences in SEQ ID NO: 1-3 or 34 or complements thereof amplifying a selected region of the

5' flanking region defined by the amplification primers, and comparing at least part of the sequence of the amplified nucleic acid with the sequence set forth in SEQ ID NO: 1-3; classifiable in class 435, subclass 6.

II. Claims 34-36, drawn to a nucleic acid molecule that comprises SEQ ID NO: 1, a recombinant DNA molecule containing a polynucleotide that specifically hybridizes to SEQ ID NO: 1, and a substantially purified molecule that "specifically binds" to a nucleic acid molecule comprising SEQ ID NO: 1, classifiable in class 530, subclass 23.1.

III. Claims 37-39, drawn to a nucleic acid molecule that comprises SEQ ID NO: 3, a recombinant DNA molecule containing a polynucleotide that specifically hybridizes to SEQ ID NO: 3, and a substantially purified molecule that "specifically binds" to a nucleic acid molecule comprising SEQ ID NO: 3, classifiable in class 530, subclass 23.1.

IV. Claims 40-42, drawn to a nucleic acid molecule that comprises SEQ ID NO: 4, a recombinant DNA molecule containing a polynucleotide that specifically hybridizes to SEQ ID NO: 4, and a substantially purified molecule that "specifically binds" to a nucleic acid molecule comprising SEQ ID NO: 4, classifiable in class 530, subclass 23.1.

V. Claims 43-45, drawn to a nucleic acid molecule that comprises SEQ ID NO: 5, a recombinant DNA molecule containing a polynucleotide that specifically hybridizes

to SEQ ID NO: 5, and a substantially purified molecule that "specifically binds" to a nucleic acid molecule comprising SEQ ID NO: 5, classifiable in class 530, subclass 23.1.

VI. Claims 46-48, drawn to a nucleic acid molecule that comprises SEQ ID NO: 26, a recombinant DNA molecule containing a polynucleotide that specifically hybridizes to SEQ ID NO: 26, and a substantially purified molecule that "specifically binds" to a nucleic acid molecule comprising SEQ ID NO: 26, classifiable in class 530, subclass 23.1.

VII. Claim 49, drawn to a substantially purified molecule that specifically binds to *cis* elements, classifiable in class 530, subclass 24.1.

VIII. Claims 50-53, drawn to a method of treating glaucoma comprising administering an agent capable of binding a cis element located within SEQ ID NO: 1, classifiable in class 514, subclass 44.

IX. Claims 70-73 and 78, drawn to a nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID NO: 33 and its complement, a region of SEQ ID NO:33 or its complement that specifically hybridizes to a nucleic acid possessing the C to T substitution of the TIGRmt11 sequence variant and a region of SEQ ID NO: 33 or its complement that specifically hybridizes to a nucleic acid possessing the **C to T** substitution of the TIGRmt11 sequence variant but does not specifically hybridize to a nucleic acid that does not possess the

TIGRmt11 sequence variant, and vectors, cells, and kits thereof, classifiable in class 536, subclass 23.1.

X. Claims 79-81, drawn to a nucleic acid comprising a nucleotide sequence selected from the group consisting of one of SEQ ID NO: 1-3 or 34, and a fragment of SEQ ID NO: 1-3 or 34 that possess a functional regulatory region, and cells and vectors thereof, classifiable in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

a. The product inventions of Groups II-VII, IX and X and the method inventions of I and VIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product inventions, drawn to various nucleotide sequences of SEQ ID, are disclosed in the instant specification as being capable of uses in materially different processes from the claimed methods. The specification at p. 25, lines, lines 5-11 considers other methods of use, stating that "[w]here one or more of the agents is a nucleic acid molecule, such nucleic acid molecule may be sense, antisense or triplex oligonucleotides corresponding to any part of the TIGR promoter, TIGR cDNA, TIGR intron, TIGR exon or TIGR gene." Also, the specification at p. 30, line 15-p. 32, line 9, notes that apart from their diagnostic or prognostic uses, the various claimed nucleotide

sequences may be used for obtaining other TIGR nucleic acid molecules of non-human animals (particularly, cats, monkeys, rodents and dogs).

b. The product inventions of Groups II-VII, IX and X, drawn to different nucleotide sequences, are each unrelated, one to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case a claimed nucleotide sequence is not disclosed as capable of use together with another claimed nucleotide sequence. Furthermore, the products have different effects, because they have different molecular structures, as indicated by their different nucleotide sequences.

c. The method of treatment invention of Group VIII and the methods of diagnosing, prognosing, detection of binding nucleic acids, detecting sequence variation of TIGRmt11 and detecting polymorphism of Group I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treatments by administering an agent capable of binding a cis element located within SEQ ID NO: 1, and the various methods of detecting polymorphisms by binding assays have different modes of operation, different functions and different effects, and are not disclosed as capable of use together.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A Claims 1-33 and 54-69, drawn to methods for diagnosing glaucoma and steroid sensitivity and prognosing glaucoma;

B Claims 74-77 drawn to a method comprising detecting the presence or absence of the characteristic TIGRmt11 sequence variation comprising contacting, with a sample, a labeled nucleic acid comprising SEQ ID NO: 33, or regions thereof;

C Claims 82-84, drawn to a method for detecting the specific binding of a molecule to a nucleic acid comprising providing a nucleic acid comprising a nucleotide sequence selected from the group consisting of one of SEQ ID NO: 1-3 or 34, and a fragment of SEQ ID NO: 1-3 or 34 that possess a functional regulatory region;

D Claims 85-89, drawn to a method for detecting TIGRmt11 sequence variation comprising amplification of a region containing the **T to C** substitution of the TIGRmt11 sequence variant and a kit thereof.

a. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 90 is generic.

b. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

c. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

d. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Claims 49 and 53 are generic to a plurality of disclosed patentably distinct species comprising:

E a *cis* element characteristic of PRL-FP111

F a nucleic acid that comprises a glucocorticoid response *cis* element

G a *cis* element characteristic of GR/PR

H a shear stress response *cis* element

I a *cis* element characteristic of CBE

J a *cis* element capable of binding NFE

K a *cis* element capable of binding KTF.1-CS

L a *cis* element characteristic of PRE

M a *cis* element characteristic of ETF-EGFR

N a *cis* element capable of binding SRE-cFos

O a *cis* element characteristic of Alu

P a *cis* element capable of binding VBP

Q a *cis* element characteristic of Malt-CS

R a *cis* element capable of binding ERE

S a *cis* element characteristic of NF-mutagen

T a *cis* element capable of binding myc-PRF

U a *cis* element capable of binding AP2

V a *cis* element capable of binding HSTF

W a *cis* element characteristic of SBF

X a *cis* element capable of binding NF-1

Y a *cis* element characteristic of NF-MHCIIA/B

Z a *cis* element capable of binding PEA1

AA a *cis* element characteristic of ICS

BB a *cis* element capable of binding ISGF2

CC a *cis* element capable of binding zinc

DD a *cis* element characteristic of CAP/CRP-galO

EE a *cis* element capable of binding AP1

FF a *cis* element capable of binding SRY

GG a *cis* element characteristic GC2

HH a *cis* element capable of binding PEA3

II a *cis* element characteristic of MIR

JJ a *cis* element capable of NF-HNF-1

KK a nucleic acid molecule that comprises a thyroid *cis* element

LL a *cis* element capable of binding NFκB

a. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

b. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC), Ph.D.*, whose telephone number is (703) 308-9355.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

11. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technical Center 1600
September 19, 2000

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER